



USES AND MISUSES OF THE QALY: ETHICAL ISSUES WITH QALYS AND ALTERNATIVE MEASURES OF VALUE

Value assessment in general, and the use of cost-effectiveness in particular, is receiving renewed interest as a tool for controlling health care spending. Currently, the most common method for determining incremental cost-effectiveness of healthcare interventions is based on a calculation of quality-adjusted-life-years (QALY). While the model has a basic appeal for making population-level decisions (by reducing patient populations to single, aggregate numeric values), it also poses several significant concerns from the vantage point of patient-centeredness and efforts to preserve access to needed care for individual patients and people with disabilities.

WHAT IS A QALY?

The QALY is a measure developed by health economists to measure and compare the benefits of healthcare interventions for cost effectiveness analyses relied on to allocate health care. The theoretical underpinning of the QALY is that something as ephemeral as quality of life can be measured and distilled down to a single number. Of course, quality of life is a concept that philosophers, scientists, and policy-makers have struggled with through the ages, making it difficult to imagine that the QALY could capture the evanescent nature and value of a person's life in a single measure.

WHAT IS THE METHODOLOGY FOR A QALY?

Traditional or conventional QALYs are measured using several different survey instruments that are designed to assess how much patients value different health conditions or "states." Many individuals included in population-based surveys can only imagine their response to theoretical scenarios and may be unable to realistically answer how much they value their lives in a particular state of health or what they are willing to trade to treat a hypothetical health condition or symptom. The methodological difficulty in measuring patient preferences becomes clear when examining the sheer number of survey instruments and methods to measure QALYs. Indeed, research has shown that using different scales can yield wildly different results. The use of surveys to cast a wide net to construct a single, average measure of patient preference does not reflect the wide heterogeneity of patient preferences.

WHAT ARE THE ETHICAL IMPLICATIONS OF QALYS?

There are serious ethical concerns with how QALYs are developed and ultimately used. For example, it is well known that QALYs fall short in measuring health preferences for patients with chronic diseases and disabilities. QALYs place greater value on years lived in full health, or on interventions

that prevent loss of perfect health while discounting gains in health for individuals with chronic illnesses. From an ethical perspective, valuing “perfect health” over pre-defined “less than perfect” states of health is fraught with issues. Our nation’s constitutional foundation of equality and our public policies such as Emergency Medical Treatment and Labor Act (EMTALA), a federal law that requires anyone coming to an emergency department to be stabilized and treated regardless of their insurance status or ability to pay, indicates our ethic to support patients and people with disabilities to maximize their individual potential for health, not a pre-defined definition of health status. To define a life as less valuable because a person’s unique circumstances deviate from “average” puts that American ethic at risk. An individual living with a chronic condition may be just as satisfied with their life as another individual with perfect health, and should not be afforded less access to treatment. The reliance of QALYs on generic measures aggregated across populations is at odds with the movement toward personalized medicine and achieving outcomes that matter to patients, also known as patient-centered outcomes.

HOW ARE QALYS MISUSED?

Despite widely acknowledged limitations of the QALY, several health technology assessment (HTA) organizations use QALYs as the theoretical underpinning for assessing the “value” of healthcare interventions. For example, both the Institute for Clinical Effectiveness Review’s (ICER) Value Assessment Framework and the Second National Panel on Cost-Effectiveness endorse the use of QALYs in valuing healthcare interventions which provide a reference to insurers for coverage decisions that impact clinical decision-making. In another example, in 1990, the Oregon Health Services Commission developed a prioritized list that ranked the relative value of healthcare condition-treatment pairs to determine what services would be covered by their Medicaid program. Just over 1,000 Oregonians were surveyed to develop the preference weights required by the selected quality assessment tool, leading to a final recommendation that ranked tooth capping higher than emergency appendectomy and recommended against life support for very low birth-weight babies. Eventually, in 1992, the U.S. Department of Health and Human Services rejected the state of Oregon’s request to proceed with their prioritized list based on explicit cost-effectiveness ratios derived from QALYs, citing the potential for the Oregon prioritized list to discriminate against people with disabilities in violation of the Americans with Disabilities Act.

WHAT ARE ALTERNATIVES TO QALYS?

Organizations representing patients and people with disabilities are engaged in efforts to promote patient engagement in the development of value frameworks and assessments of treatment value. For example, the National Health Council engaged patient stakeholders and others to create a Patient-Centered Value Model Rubric to help evaluate the patient-centeredness of value models and to guide value model developers on the meaningful incorporation of patient engagement throughout their processes. Additionally, *FasterCures*, a non-partisan and non-profit think tank, has partnered with Avalere Health to develop the Patient Perspective Value Framework (PPVF) incorporating measures of benefits and costs in the context of patients’ personal goals and preferences to assess the value of different health-care treatment options. These efforts represent a growing emphasis on the

development and use of patient-centered outcome measures as indicators of improving quality in public health care programs. The goal of these and many other ongoing efforts is to develop and implement a new paradigm for value assessment that prioritizes the delivery of care that is most valuable to the individual patient and, in many cases, that incorporates cost concerns that go beyond the scope of purely medical costs to also consider personal, family and societal costs associated with the condition being treated such as transportation needs, caregiving, loss of productivity and work, or increased risk of future disability.

HOW DO WE PROTECT PATIENTS AND PEOPLE WITH DISABILITIES, WHILE ADDRESSING COST CONCERNS?

Policymakers recognize the dangers of misusing cost-effectiveness standards in ways that undermine high-quality, individualized care. For example, the Patient Protection and Affordable Care Act (ACA) explicitly prohibits PCORI from using the cost-per-QALY as a threshold to establish what type of health care is cost effective or recommended, and further restricts the use of QALYs by precluding their use as a threshold to determine coverage, reimbursement, or incentive programs” in the Medicare Program. Yet, last year policymakers and thought-leaders showed renewed interest in policies that rely on use of cost-effectiveness standards with the proposed Medicare Part B Drug Payment Program. There is growing concern that standardized care decisions create barriers to certain treatments for individuals that don’t meet “average” thresholds, leading to increased costs when treatments fail the patient. When patients cannot access treatments that work for them, our health care system bears the cost of reduced treatment adherence, increased hospitalization and other acute care episodes, as well as the societal costs of increased disability over time. In this age of personalized medicine, we can reduce costs by better targeting treatments shown to work on patients with similar characteristics, needs and preferences, thereby avoiding the waste of valuable resources on care that patients do not value.

PIPC aims for policymakers to focus on health care payment and delivery reforms that activate and engage patients and people with disabilities and that support shared decision-making between patients and people with disabilities, and their providers. We believe that solutions that center on delivering care that patients and people with disabilities value are the best approaches to improving overall health care efficiency and quality.